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ALLIANCES IN MEXICO
AND SRI LANKA

June 24, 2021

VIA ECF

The Honorable Robert Kugler
Senior United States District Court Judge
District of New Jersey

The Honorable Karen M. Williams
United States Magistrate Judge
District of New Jersey

The Honorable Thomas Vanaskie
Special Discovery Master
Stevens & Lee

Re: In re Valsartan, Losartan, and Irbesartan Products Liability Litigation
Case No. 1:19-md-02875-RBK-KW

Dear Judges Kugler, Williams, and Vanaskie:

This letter is to provide Defendants' positions with respect to the topics on the agenda for the conference with the Court on June 25, 2021.

1. Baohua Chen's Custodial File Production and Deposition Schedule

The ZHP Parties' review of Mr. Chen's custodial file is in progress, and the ZHP Parties are diligently working toward the production deadline of July 12 set by the Court last week. The ZHP Parties are evaluating Judge Vanaskie's ruling issued on June 22 denying their motion for a protective order.

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2. ZHP Production of Documents Related to Plaintiffs' New Discovery Requests

The ZHP Parties and Plaintiffs had a productive meet and confer conference on Wednesday, June 23, 2021, in relation to an inquiry letter from Plaintiffs dated Monday, June 21, 2021, regarding the ZHP Parties' productions in response to Plaintiffs' new discovery requests.

During the conference, the ZHP Parties answered Plaintiffs' questions related to their collection and production processes—such as the process used to identify and collect hardcopy documents and the scope of available ESI for certain custodians. The ZHP Parties also provided the Bates ranges for certain categories of documents requested by Plaintiffs (including nitrosamine testing records) and agreed to investigate and provide additional information on the scope of electronic data available for certain custodians. However, as previously explained to Plaintiffs and the Court, because the ZHP Parties maintain many of the core records at issue in this case in hardcopy format—including laboratory notebooks and testing data—the ZHP Parties' productions include a significant number of hardcopy documents (to date, nearly 40,000 hardcopy documents totaling over 300,000 pages).

In addition, the ZHP Parties provided information to Plaintiffs on the production format used for certain unrenderable file types and agreed to identify certain additional categories of documents by Bates numbers in order to assist the Plaintiffs in locating documents. Finally, Plaintiffs brought to the ZHP Parties' attention some issues related to the production of documents regarding broken or damaged employee electronic devices, and the ZHP Parties agreed to produce such responsive documents by June 25, 2021.

As explained during the conference last week, the ZHP Parties are continuing to perform quality checks of their most recent productions. The ZHP Parties anticipate producing the additional documents identified during this process by July 2, 2021. In addition, the ZHP Parties

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are committed to working cooperatively with Plaintiffs to address any additional questions that arise as Plaintiffs continue their review of the ZHP Parties' recent productions.

3. Hetero Drugs Ltd. and Hetero Labs Ltd. Discovery

A. Privilege Log

Defendants Hetero Drugs Ltd. and Hetero Labs Ltd. (collectively, "HLL") have thus far made two document productions to de-designate documents previously deemed privileged, and anticipates a subsequent document production to de-designate additional documents, early next week.

On May 5, 2021, in response to specific objections raised by Plaintiffs, HLL de-designated several documents that were previously deemed privileged, and made a subsequent de-designation of documents on May 17, 2021. HLL is presently conducting a re-review of the remaining documents in its privilege log that Plaintiffs did not specifically object to, in order to determine which additional documents may be de-designated. HLL anticipates making this document production by early next week. On June 22, 2021, the parties met and conferred on this issue by telephone. During that teleconference, Counsel for HLL explained that it intends to de-designate additional documents, and will subsequently have a follow-up meet and conferral regarding all documents which HLL is continuing to assert a privilege. It is HLL's position that at that time, to the extent that the parties cannot agree on which documents are to remain privileged, would judicial intervention be necessary. Accordingly, HLL respectfully submits that this matter is not ripe for judicial intervention at this time, as HLL continues to work with Plaintiffs regarding which documents are to remain privileged.

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B. Outstanding Discovery

HLL provides an update to the Court regarding the status of discovery deficiencies previously raised by Plaintiffs with respect to HLL's document productions. Since the last Case Management Conference on June 16, 2021, HLL has made 3 additional document productions to Plaintiffs with respect to documents Plaintiffs state they cannot locate in HLL's document productions. Specifically, on June 18, 2021, HLL produced documents pertinent to the process development of the Valsartan product. Thereafter, on June 21, 2021, HLL produced a Quality Agreement between the API and Finished Dose Units of HLL, as well as API Audit Reports and Chromatograms of GC analysis for the affected Valsartan product. Furthermore, on June 23, 2021, HLL produced obsolete/discontinued Standard Operating Procedures requested by Plaintiffs and referred to by Plaintiffs as "general housekeeping," as well as the remaining Chromatograms of HPLC analysis for the affected Valsartan product. At this time, there remain very few, discreet documents outstanding.

Additionally, on June 18, 2021, the parties met and conferred by telephone and mutually agreed to adjourn the depositions of HLL's remaining 30(b)(6) and fact witnesses without rescheduling them. HLL agreed to produce the remaining 3 witnesses at a later date without objection, if necessary, and further agreed to stipulate to the authenticity and business records nature of documents produced in HLL's May 20, 2021 document production, and all subsequent document productions. The intention of the agreement was to allow the parties to rely upon the documents produced without the need for witness testimony for admissibility purposes. As a result, we do not anticipate that there will be a need for further depositions of HLL witnesses.

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Accordingly, HLL is working in good faith with Plaintiffs regarding de-designation of several HLL documents that were previously deemed privileged, and is further continuing to address the narrow remaining discovery deficiencies raised by Plaintiffs.

4. Plaintiffs Fact Sheets/Show Cause Listings

A. Cases Addressed at the June 3, 2021 Case Management Conference

Defendants note that the Court issued three show cause orders returnable at the June 3, 2021 Case Management Conference:

- *Darris Knox v. CVS Health, et al.*, - 20-cv-16419
- *Julie Sundermeir v. Aurobindo Pharma, Ltd., et al.*, - 21-cv-01075
- *John Wilcox v. Mylan Laboratories Ltd., et al.*, - 20-cv-17939

The issues in the *Wilcox* matter are resolved and that show cause order may be withdrawn. The *Knox* and *Sundermeir* matters are not resolved and Defendants request the show cause hearing proceed in those matters.

B. Second Listing Cases – Order to Show Cause Requested

Pursuant to CMO-16, the Plaintiff Fact Sheets in the below cases are substantially incomplete and contain core deficiencies. Each of these three cases were previously listed on the agenda for a prior CMC. Defendants provided a list including these cases and identified deficiencies to Plaintiffs' leadership counsel for distribution on June 16, 2021. In lieu of a global meet and confer, Defendants reached out to individual counsel for each case and have been available for further meet and confers as needed. Accordingly, Defendants request that an Order to Show Cause be entered in each of these cases, returnable at the next case management conference, as to why the case should not be dismissed.

Defense counsel will be prepared to address the individual issues with respect to each of these cases, to the extent necessary, during the June 25, 2021 Case Management Conference:

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Notice Sent |
|----|--|------------------|--|---|------------------------|
| 1. | DeClerk, Thomas v. Hetero Drugs, Ltd. | 21-cv-01016 | Brent Coon & Associates Bob.schwartz@bcoonlaw.com | No PFS Filed | PFS Due 3/22/21 |
| 2. | Stone, Alan v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al | 20-cv-15654 | Watts Guerra LLP | I.C Failed to respond. Name and address of physician that prescribed Valsartan from 2010 to 2016, 01/23/2018, and Aug to Nov 2018. | 01/12/21 |
| 3. | Stewart, Pamela v. Zhejiang Huahai Pharmaceutical Co., Ltd., et al | 20-cv-03788 | Erlanger Law | I.D. Failed to attach records showing alleged injury III.G. Failed to respond - Medical expenses XII. Plaintiff has not provided a signed and dated declaration | 12/22/2020 |

C. First Listing Cases – Remaining Core Deficiencies

The following Plaintiff Fact Sheets contain core deficiencies which remain unresolved. Defendants provided a list including these cases and identified deficiencies to Plaintiffs on June 16, 2021, and have been available for further meet and confers as needed. This is the first time these cases have been listed on this agenda. Accordingly, Defendants are not requesting orders to show cause with respect to any of the below cases at this time and will continue to meet and confer to resolve these deficiencies.

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| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | Deficiency Sent |
|----|--|------------------|---|--|-----------------|
| 1. | Aloian, Debbie, Individually and as Representative of Richard Aloian, Deceased v. Hetero Drugs, Ltd., et al. | 21-cv-02119 | Watts Guerra, LLP pboldt@wattsguerra.com | <p>III.B.3.a – Plaintiff did not state whether the referenced packaging, packaging inserts, and dosing instructions are in Plaintiff’s possession. If so, please produce a copy of said packaging, packaging inserts, and dosing instructions.</p> <p>III.B.4.a – Plaintiff did not identify each person who gave the decedent instructions about Valsartan.</p> <p>III.G.b – Plaintiff still did not provide the date of the identified claimed medical expense in the Amended PFS.</p> <p>III.G.c – Plaintiff did not provide the monetary amount of the identified claimed medical expense in the Amended PFS.</p> <p>IV.D.3 – Plaintiff did not provide the approximate start date for usage of the following medication: Spironolactone.</p> <p>XI.A.1 – No health care authorization was produced for the following health care provider: Nova Healthcare Adm.</p> | 5/24/21 |

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| | | | | | |
|----|---|----------------------|---|---|------------|
| 2. | Henton, Cassandra v. Aurobindo Pharma, Ltd., et al. | 21-cv- 02338 | Nabers Law Firm snabers@naberslaw.com | PFS substantially incomplete; no Amended PFS filed | 05/11/2021 |
| 3. | Knight, Gloria v. Hetero Labs, Ltd., et al. | 21-cv- 06383 | Williams Hart Boundas Easterby, LLP sbrahmbhatt@whlaw.com | *The Amended PFS is due 6/25/2021. This case can be removed from the list if the deficiencies are cured prior to the end of month conference. III.B.3.a – Plaintiff failed to state whether the referenced prescription packet of written instructions she received from the pharmacy is still in Plaintiff’s possession. If so, please produce a copy of said written instructions. III.G.c – Plaintiff did not provide the monetary amounts of the identified claimed medical expenses. XI.B.18 – No corresponding billing records were produced for the identified claimed medical expenses. | 6/11/2021 |
| 4. | Righteous, Worikeena v. Mylan et al. | 2020 - CV- 414 | PWB Law Group, LLC | Incomplete PFS, no authorizations or records | 04/23/21 |

D. First Listing Cases – Failure to File Plaintiff Fact Sheet

The following Plaintiff has failed to file a timely Plaintiff Fact Sheet. Defendants provided a list including this case to Plaintiffs on June 16, 2021, and have been available for further meet and confers as needed. This is the first time this case has been listed on this agenda. Accordingly,

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Defendants are not requesting orders to show cause with respect to this case at this time and will continue to meet and confer to resolve these deficiencies.

| | Plaintiff | Civil Action No. | Law Firm | Deficiencies | PFS Due Date |
|----|----------------------------------|------------------|----------------------------------|--------------|--------------|
| 1. | Bryant J. Brooks v. Mylan et al. | 1:19-cv-15768 | Law Offices of Kenneth W. DeJean | No PFS filed | 09/25/2019 |

5. Defendants' Treating Physician Deposition Protocol Should Be Approved

The parties participated in a further meet and confer on the draft treating physician deposition protocol on June 11 (no Plaintiffs' counsel appeared for a previously scheduled meet and confer on the protocol on June 9, without explanation). The parties did not reach any meaningful agreements during this meet and confer. On June 17, Plaintiffs provided Defendants with a new version of the protocol with additional redline changes. Defendants accepted one of these changes but cannot agree to most of them. The current draft is attached here as **Exhibit A**.

The key disputes between the parties are as follows:

- **Limitation on Treating Physician Depositions:** The most significant dispute is Plaintiffs' proposal that the parties should be limited to deposing only two treating physicians (one prescribing physician and one additional treating physician) in each bellwether case.¹ Defendants strongly oppose any arbitrary limitation on the permissible number of treating physician depositions. No such limitation has been imposed in numerous MDLs. *See, e.g., In Re Xarelto (Rivaroxaban) Products Liability Litigation*, MDL No. 2592 (E.D. La.) (CMO #1). Nor have Plaintiffs provided any justification for such a limitation—except that they apparently disagree with the Court's order that full discovery should proceed in

¹ Notably, Plaintiffs' proposal does not explain how these two treating physicians would be identified, given that the parties would undoubtedly select different physicians to depose if limited to only two.

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all 28 bellwether cases and do not want to expend the resources required to work up each case, as the Court has specifically ordered the parties to do. Defendants would be prejudiced in their ability to prepare these cases for trial if they were unable to elicit key information from Plaintiffs' treating physicians, which will be relied upon by Defendants' experts. Any arbitrary, across-the-board limit on the number of treating physicians depositions would be both unnecessary and unfair to Defendants. No two cases are exactly the same, and while some cases may be adequately worked up with two or three medical providers, other cases may involve more complex medical histories and necessitate more substantive discovery. Under Plaintiffs' proposal, the parties would be forced to choose in some instances between taking a Plaintiffs' primary care physician, who may have the most knowledge about the patient's medical history and co-morbidities, and a specialist who prescribed the medication. Defense counsel, like Plaintiffs' counsel, have no desire to waste resources and have no intention of noticing depositions that are not important to the defense of Plaintiffs' claims. If defense counsel seek an unreasonable number of depositions or to depose tangential witnesses, Plaintiffs' counsel may seek relief via a protective order as in any case. The fact that these 28 cases have been coordinated into an MDL for efficiency's sake, does not provide a basis for arbitrarily restricting key discovery that would be allowed in any typical product liability case. In attempt to explore potential compromises, Defendants have asked whether Plaintiffs would agree to a more reasonable limitation or if they would agree to depositions above two if Defendants pay for them, but Plaintiffs' counsel have refused to entertain these potential compromises.

- **Contact with Physicians by Employees of Defendants:** Plaintiffs seek Defendants' disclosure of any contacts with treating physicians occurring during the ordinary course of business, such as calls by sales representatives, within 7 days (or potentially fewer) of each physician's deposition. Defendants oppose such a burdensome and unnecessary requirement. Any such contacts by employees of Defendants unaffiliated with the litigation, on matters unrelated to any particular Plaintiff (of whom the representatives would have no knowledge), should not be considered ex parte communications, as they plainly do not implicate the same potential concerns as direct communications between defense counsel and treating physicians. Furthermore, Plaintiffs are free to explore any such communications during the depositions.
- **Ex Parte Communications by Plaintiffs' Counsel:** Defendants propose that Plaintiffs disclose the occurrence of ex parte communications with treating physicians and produce documents related to such communications within 48 hours of the physician's deposition. Plaintiffs' counsel will not agree to this reasonable requirement and have not proposed any compromise.
- **Use of Treating Physicians as Experts:** Defendants do not plan to communicate intentionally with retained experts about Plaintiffs they may have treated and are open to a reasonable provision to prevent such intentional communications, particularly in bellwether cases. That being said, Defendants oppose Plaintiffs' broad proposed language, which would require Defendants to be familiar with all treating physicians identified by any of the more than 600 Plaintiffs in this litigation.

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- **Order of Questioning/Scheduling of Depositions:** The parties have agreed broadly that the order of questioning of treating physicians by Plaintiffs and Defendants will alternate across Plaintiffs and treaters. However, Plaintiffs' proposal is inextricably linked to their proposal that the parties be permitted to depose only one prescriber and one other treating physician. Again, Defendants vehemently oppose this proposal. Defendants also oppose Plaintiffs' proposal that Plaintiffs handle all scheduling, as it would make Defendants entirely beholden to Plaintiffs for depositions sought by Defendants being scheduled in a timely manner. It would be far more logical for the noticing/lead questioning firm for each deposition to handle scheduling, and there would be no risk of ex parte communications if such scheduling were handled by a non-attorney staff member, as Defendants have proposed.

6. Judge Kugler Has Already Declined to Winnow the Agreed Upon Bellwether Pool

Plaintiffs have indicated they intend to renew their request, yet again, to winnow the bellwether trial pool of 28 that the parties previously agreed to. However, Judge Kugler has already declined this request, and instructed the parties to proceed with working up the 28 bellwether cases as originally agreed. Specifically, at the March 31, 2021 CMC, the Court declined to winnow the bellwether pool, at least prior to the completion of the initial round of treating physician depositions. The Court made clear that it had contemplated full discovery on all bellwether Plaintiffs. The Court explained: "M]y contemplation months ago was that there would probably be about 40 cases in this and you've agreed to 28, that's fine, I don't take issue with that. I think my words at that time was you're going to need armies of lawyers to continue on this parallel track that you want to do. I still expect you're going to need armies of lawyers to do this. So my contemplation was full discovery on these plaintiffs at the time and I still think my contemplation is full discovery of all the plaintiffs."

During the June 10 meet and confer regarding the treating physician deposition protocol, Plaintiffs' counsel stated that they will again seek to winnow the bellwether pool, even though most bellwether Plaintiff depositions have not been completed (although nearly all are now

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scheduled), and no treater depositions have taken place. Nothing has changed, however, since Judge Kugler ruled on this issue three months ago to warrant a renewal of this request. Even at this early stage in most cases, it appears a “natural winnowing” will still occur before trial. For example, bellwether Plaintiff James Suits has unfortunately recently passed away, and his family has indicated they may not continue to pursue the case. Whether other Plaintiffs may drop out of the pool is not within Defendants’ control. However, as the Court has noted, if the pool is prematurely winnowed, it cannot be later expanded, as that would impact all case deadlines. Defendants’ position remains the same: full discovery should be completed in all 28 bellwether cases unless and until Plaintiffs decide to voluntarily dismiss them.

Respectfully submitted,

/s/ Seth A. Goldberg

Seth A. Goldberg

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